EXHIBIT 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ROBERT GUSTAVSEN, JOSEPH CUGINI, DEMETRA COHEN, LEE WILBURN, JACKIE CORBIN, MARY LAW and CECELIA BRATHWAITE, on behalf of themselves and all others similarly situated, Plaintiffs, v. ALCON LABORATORIES, INC.; ALCON RESEARCH, LTD.; FALCON PHARMACEUTICALS, LTD.; SANDOZ, INC.; ALLERGAN, INC.; ALLERGAN USA, INC.; ALLERGAN SALES, LLC.; PFIZER INC.; VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; BAUSCH AND LOMB INCORPORATED; ATON PHARMA, INC.; MERCK & CO., INC.; MERCK, SHARP & DOHME CORP.; PRASCO, LLC; AND AKORN, INC., Defendants.	Civil Action No. 14-CV-11961-MLW

BEFORE THE HONORABLE MARK L. WOLF
UNITED STATES DISTRICT JUDGE

MOTION HEARING
October 30, 2015

John J. Moakley United States Courthouse
Courtroom No. 10
One Courthouse Way
Boston, Massachusetts 02210

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P R O C E E D I N G S

(The following proceedings were held in open court before the Honorable Mark L. Wolf, United States District Judge, United States District Court, District of Massachusetts, at the John J. Moakley United States Courthouse, One Courthouse Way, Courtroom 10, Boston, Massachusetts, on Friday, October 30, 2015.)

THE COURT: Would counsel please identify themselves for the Court and for the record.

02:58 MR. DeMOURA: Good afternoon, your Honor. Kenneth DeMoura from DeMoura Smith for the plaintiffs.

MR. CORNFELD: And Rick Cornfeld. I'm from St. Louis, and I represent the plaintiffs.

MS. PERINI: Emily Perini, Perini-Hegarty & Associates, for the plaintiffs.

MR. STRAUSS: Good afternoon, your Honor. Steve Strauss, Randy Soriano and Amy Mariani for defendants Merck and Prasco.

MS. JACXSENS: Your Honor, Christiana Jacxens,

02:58 Greenberg Traurig, along with my colleague Dave Thomas for defendants Sandoz, Inc., Alcon Laboratories, Alcon Research and Falcon.

MS. BLADOW: Good afternoon, your Honor. Robin Bladow for Pfizer. With me for Pfizer is Sean Paisley and Dave Clancy.

MR. MUEHLBERGER: Good afternoon, your Honor. James Muehlberger appearing on behalf of Allergan, Aton Pharma, Bausch and Lomb and Valeant.

THE COURT: Who else?

MR. KILROY: John M. Kilroy, Jr., on behalf of Akorn, and Joseph Crimmins also on behalf of Akorn.

THE COURT: Okay. If you're not within the enclosure, I assume you're not going to be speaking, so I think I've got enough of you to try to keep straight.

02:59 I apologize both for the time it has taken to schedule this hearing and for my starting almost a half hour late. There are many motions on behalf of many defendants, and it's always my goal to decide them orally at the hearing, which is my goal today. We'll see whether it's going to be achieved. But it took me somewhat longer to prepare, finish preparing than I had hoped.

So we're here today with regard to the defendants' motion to dismiss. Which of you represent the generic drugmakers?

03:00 MS. JACXSENS: There are several of us, your Honor. I represent Sandoz and Falcon, who are both generic drug manufacturers.

THE COURT: I'm going to hear the motions to dismiss of the other defendants first. I think it may be useful to recognize the applicable standards. The generally applicable

standard on a motion to dismiss is that such a motion should be denied if the plaintiff has shown a plausible entitlement to relief. The complaint must contain sufficient factual matters accepted as true to state a claim that is plausible on its face. The complaint needs to be construed liberally. It has to be specific enough to permit the reasonable inference that the plaintiffs stated a plausible claim.

Under Rule 12(b)(6), the District Court may properly consider only facts and documents that are part of or incorporated into the complaint. That's *Rivera*, 575 F.3d 10, 15. However, there are narrow exceptions for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiffs' claim; or for documents sufficiently referred to in the complaint. That's *Watterson*, 987 F.2d at 3, 4.

When I'm deciding a 12(b)(1) motion, alleging subject matter -- alleging lack of subject matter jurisdiction, I also have to construe the complaint liberally and treat all well-pleaded facts as true, giving the plaintiff the benefit of all reasonable inferences, but I don't have to accept as true legal conclusions couched as factual allegations. I think importantly -- and we can go over this again because I'm going to segment the argument.

With regard to the preemption argument, preemption as I understand it is an affirmative defense. And a leading First

Circuit case on when an affirmative defense is sufficient to justify granting a motion to dismiss is *Blackstone Realty*, 244 F.3d 193. The First Circuit wrote that the facts establishing the defense must be clear on the face of plaintiff's pleadings. Furthermore, review of the complaint together with any other documents appropriately considered under Rule 12(b)(6) must leave no doubt that the plaintiff's action is barred by the certain defense.

So that's the legal framework I start with. If you think it's not accurate or complete in every relevant regard, you can tell me.

The threshold question is whether the plaintiffs have standing. It's my present view that they have adequately alleged standing for the purpose of the motion to dismiss. That is, standing based on economic injury in fact. I don't know if the -- it didn't appear to me the plaintiffs were seeking to establish standing based on a claim of physical injury, but maybe that could get clarified.

MR. CORNFELD: Your Honor, Rick Cornfeld --

THE COURT: Excuse me. If you address the Court in this District, you stand up.

MR. CORNFELD: I apologize, your Honor. Rick Cornfeld for the plaintiffs. That is correct. The plaintiffs are not seeking damages for physical injury.

THE COURT: Okay. Then for reasons I could explain,

it's my present view that standing is adequately alleged. If the defendants want to be heard on that, I'll hear you, but I'm hoping to have the major argument focused on the preemption matter. Would the defendants, any or all of them, like to address standing?

MS. BLADOW: Yes, your Honor.

THE COURT: And if you don't mind -- and even if you do mind -- please remind me who you are.

MS. BLADOW: Absolutely, your Honor. Robin Bladow for Pfizer. We would like to address standing. What we've done, just to make things clear, there's a lot of lawyers here, we've divided the argument up based on topic.

THE COURT: Okay.

MS. BLADOW: So you get the best prepared person, hopefully, to respond to each of the issues. If your Honor does want to give us some indication of why you believe there, in fact, is standing, because we believe very strongly that there isn't.

THE COURT: In fact, I usually do. As I understand it, the plaintiffs allege that the eyedrops at issue here or the droppers dispense more than necessary and more medication than the eye can absorb and they do that so consumers will have to buy more, spend more, and the defendant companies will make more money. They allege that there are scientific studies that support their theory, and they quote one of the Akorn

executives saying that that is the motive for having 30 or 45 microliters dispensed rather than the 15 that they say the studies show is efficacious.

I think I can consider those materials because they're referenced in the complaint. Count 1 alleges a violation of Mass. General Law Chapter 93A. And Chapter 93A prohibits unfair and deceptive practices. It's very broadly interpreted by the Massachusetts courts. Anything that's in the penumbra of established legal theory can be deceptive or unfair.

03:08 So it appears to me, at the moment, without giving you all the details, that they've adequately alleged a Chapter 93A claim and as well the elements for standing based on economic injury. They essentially allege that they paid more for the prescription eye medicine than they should have. They overpaid, and the defendants profited.

So, to me, that is not an implausible claim generally, and they actually cite the statement of one of the defendants from Alcon, that that was a motive. So that's a compressed version of my present reasoning, tentative reasoning.

03:09 MS. BLADOW: Thank you, your Honor. I appreciate that there's a lot of paper before your Honor and there's a lot of cases that we cited. I hope your Honor had an opportunity to review the *Cottrell* opinion for the District of New Jersey, Judge Wolfson's opinion.

THE COURT: I did read it, but it doesn't state the

standard under Chapter 93A. If he accurately understood the law in the Third Circuit, it's not the law in Massachusetts.

MS. BLADOW: Well, the decision was based on Article III, and injury in fact you must show under Article III. What we have here, and I think what I urge your Honor to consider, is the fact that under a 93A or under any consumer protection statute or any type of unfair businesses claim, the claim is generally, Okay. I bought a product, and I spent ten dollars on that product, but I didn't get what was represented to me. I didn't get my ten dollars' worth. I only got seven dollars' worth. You told me it was going to do X, Y and Z. It only did X and Y, so I get my three dollars back because it didn't perform Z. That's one way. That's not what plaintiffs are alleging here.

The other situation might be where you purchase a product and you pay your ten dollars for it, and then you're harmed in some way; the product caused you illness, it caused physical harm. That's another way that you might be injured. But the injury that's alleged here is injury I have not seen in any other case, and I believe that your Honor would be the first to permit it to go forward under Article III. And here is why.

THE COURT: It wouldn't be the first time that I was the first judge to do something. I was the first judge to order the FBI to disclose the existence of a high echelon Mafia

informant, and now it's a major motion picture.

MS. BLADOW: But let me explain to your Honor why I think that would be a grave mistake here. The plaintiffs went in and they purchased a product and they got exactly what was represented to them and exactly what they paid for. There's no harm. They got the doses they needed. They got effective medication.

THE COURT: They're saying they got three times or two times the dose.

03:11 MS. BLADOW: But they got what they were promised, and they got what they paid for. The fact they got more is not injury to them. There's no harm. Their entire theory is premised on the notion that had there been less volume in the bottle that the bottle necessarily would have cost less. And frankly, your Honor --

THE COURT: Actually, I don't think they have to. This is why I think the standard is very important. You know, you're honing in on just the right thing. At this point I have to decide whether they've alleged specific facts to state a

03:12 plausible claim. And they allege, are going to argue -- they do argue, as I understand it, that at least implicitly, the medication would have cost less. If they bought a bottle that was half as big, it would have cost half as much. That's not, even without the Alcon statement, in my present view, inherently, it's not implausible. That's A. And B, they

reference a statement of one defendant that's consistent with that.

MS. BLADOW: Well, but your Honor, it's not a statement of fact. You have to agree that it's not a statement of fact.

THE COURT: It could be.

MS. BLADOW: That the medication would have cost less? There's absolutely no requirement anywhere in the law, and counsel hasn't cited any, that would require these companies to charge less under the circumstances.

THE COURT: Why is it obvious that it wouldn't cost less? In other words, we might develop the arguments, and indeed, I don't think there could be an antitrust -- I'm being somewhat -- I don't know how to say it. This is competitive industry. Usually Pfizer and Merck compete. They compete on price. They say we'll give you 15 microliters and ours will last twice as long. Doctors should prescribe Merck, not Pfizer.

MS. BLADOW: And it is a competitive industry, and the market should regulate this exact thing that counsel is raising. The market should regulate this issue. And the fact of the matter is, if defendants are forced to go and research, redesign, repackage, resubmit to the FDA these products with a smaller tip, it's pure conjecture, it really is, under *Lujan v. Defenders of Wildlife.* This is Supreme Court Article III

authority. It's pure conjecture that the price would be different. I would direct your Honor perhaps to the D.C. Circuit case, the *United Airlines* case, and we cite in our brief. That's a situation where -- I don't know if your Honor recalls it but --

THE COURT: I recall it. It's discount airline tickets.

MS. BLADOW: That's exactly what it is. And the Court said, Hold on a second. If United Airlines wasn't permitted to have these no-transfer constraints on these tickets, it would require the Court to pile speculation atop speculation in order to determine --

THE COURT: Hold on a second. Let me get that case.

MS. BLADOW: Sorry about that.

THE COURT: That's okay. Two things. That's *Dominguez*, right?

MS. BLADOW: Yes.

THE COURT: It was decided on summary judgment, not on a motion to dismiss. Do you remember that?

MS. BLADOW: It's still the same exact framework, though.

THE COURT: Of course it's not. It depends on what the evidence is.

MS. BLADOW: Here there is no evidence, there's no allegation that these defendants would in fact be required to

charge something --

THE COURT: I have to liberally construe the allegations. They cite in a journal -- it might not be true. When you get to summary judgment, the fellow might say I never said it. Although you still have a disputed fact if it's material. But you have an executive of one of these companies saying, We don't want to make the dropper dispense smaller drops because we want to make more money.

MS. BLADOW: I think we have a really hard time, and
03:15 I'm frankly a little bit surprised that your Honor is relying on that statement from an unnamed executive at one of the defendants. I represent Pfizer. It certainly doesn't say anything that Pfizer has to do. It also doesn't say anything about what the law requires companies to do in terms of pricing. I mean, I just caution your Honor because what we have here is a situation where you permit --

THE COURT: Here. Let me help you with this. You showed me a D.C. Circuit case on summary judgment.

MS. BLADOW: Only to show that the defendants --
03:16 THE COURT: I understand.

MS. BLADOW: -- have discretion in their pricing.

THE COURT: What about -- maybe I can anticipate your answer. Do you recall what the First Circuit said with regard to standing analogous relevant to this in, *In Re: Pharmaceutical Industry*, 582 F.3d --

MS. BLADOW: I sure do, your Honor. I think that's a good case to point out because I know plaintiff has relied very heavily on that case. And in that case, it falls into the category that I talked about earlier, which is, there is a misrepresentation, there is an alleged misrepresentation in that case that the drug companies were setting an average wholesale price that was false. And because that wholesale price was false, third-party payors were paying out much higher than they otherwise would.

03:16 That's not what happened here. In fact, plaintiffs don't even argue that they would not have bought the product had they known about the drop size issue. There's no misrepresentation at all. They went into these transactions, purchased a product prescribed by their doctors, no less, but purchased a product and got exactly what they paid for.

THE COURT: Did anybody -- did any of the defendants or anybody else offer the product with droppers that dispensed, say, less than 30 microliters?

MS. BLADOW: No. There aren't droppers out there that

03:17 are made as counsel and plaintiffs have argued it should be made. Your Honor, this is -- it really is opening up a huge can of worms, and I would really urge you to think about this and reconsider at least your tentative --

THE COURT: I have thought about it.

MS. BLADOW: I understand you have. But let me just

posit something for you.

I'm a consumer and I walk into the grocery store, and I look at the ketchup bottle. I decide that there's a better way -- I have some science behind me even, there's a better way to make a ketchup bottle so I can get all the ketchup out, or I can get all the toothpaste squirted out of the toothpaste container, or I have a can of hairspray that I think the diameter is too big, it goes all over the place, it doesn't go on my flat hair, and I think there's a better way to make the
03:18 product. So I'm going to buy a ticket into Article III court because I think there's a better way and I want 20 cents back on my hairspray product because the diameter of the spray is too big? That can't be what standing is here, particularly where there is no misrepresentation. The consumers got exactly what they paid for. They weren't harmed by the product.

THE COURT: I thought they were in effect arguing -- this is Chapter 93A. Is it unfair? Is it deceptive? In effect, I thought their argument was -- the way I was perhaps construing it is -- the manufacturers, the drug companies are
03:18 saying, you know, you need this eyedrop. It's been prescribed for you, and you need at least this much, 30 microliters. And they say there's evidence that the body can't absorb that much.

But the motion to dismiss standard is very important. That's why I started with it. Let me hear from the plaintiffs, and perhaps I'll give you a chance to respond.

MS. BLADOW: Okay. Thank you, your Honor.

MR. CORNFELD: Your Honor, with all due respect, if you deny this motion, you won't be the first judge who has ever found standing in a similar situation, who has ever found standing for somebody who is complaining about an unfair practice or some other illegal practice with respect to a drug that they bought and provided exactly the treatment that they were seeking.

That is what happened in the *Average Wholesale Price Litigation*. It was a claim of unfair practices. In fact, we rely on what Judge Saris did, not with respect to standing, but she -- as you may recall, she ruled that a Massachusetts named plaintiff could represent plaintiffs in other states that had similar unfair or unconscionable practice statutes, showing that that was an unfair practice claim just like ours is. The plaintiffs bought medication. The medication so far as the record shows worked. It didn't cause them any physical problems, just like us, but it cost them more money than it should have.

03:19

03:20

The other First Circuit case that found standing in a similar situation is the recent case of *In Re: Celexa*. That was last January. We just submitted that within the last week or so to your Honor.

THE COURT: Hold on a second. We should have it.

What's the citation on it, please?

MR. CORNFELD: Just one moment. I'm sorry, your Honor. I misspoke. *In Re: Nexium*, 777 F.3d 9.

THE COURT: What page?

MR. CORNFELD: 777 F.3d 9. That was an antitrust case where Nexium was accused of conspiring with generics to -- a so-called pay for delay case, where they kept the generics off the market. At page 32 --

THE COURT: Page 32?

MR. CORNFELD: Yes.

03:22 THE COURT: Let me find page 32.

MR. CORNFELD: Okay. Where the Court said, "It is undisputed that the named plaintiffs have shown that they were overcharged for at least one Nexium transaction during the class period establishing standing."

THE COURT: Hold on.

MR. CORNFELD: Cited *Baker v. Carr*, then saying the named plaintiffs thus have standing to sue for their injuries and to request under Rule 23(b)(3) that the Court allow them to represent and secure a judgment on behalf of the class.

03:22 In addition, a District Court case, *In Re: Solodyn*, which was cited just last month.

THE COURT: Did you cite that for me previously?

MR. CORNFELD: We submitted that in the last couple of weeks, and your Honor gave us grant of leave to today.

THE COURT: Okay. What page?

MR. CORNFELD: On page star 14 -- your Honor, this is another so-called pay for delay case. And the Court states, The Court concludes that the named end payors have Article III standing. It is undisputed that the end payors allege that they paid for Solodyn at prices that were inflated due to defendant's alleged anticompetitive actions, and such allegations constitute a cognizable monetary injury. It is further undisputed that the remedy sought, compensatory and injunctive relief for these overpayments, is likely to redress this injury.

03:23

So whether there's a misrepresentation in a case where the claim is unfair, an unfair practice, it's irrelevant for standing. Standing is whether the plaintiff was injured, and we believe we have adequately alleged an economic injury and we believe we have adequately alleged the basis for saying that with a lot of literature.

THE COURT: Well, all right. I mean, I do think that it's related to the 93A claim that you would have to be injured by some actionable wrong, and these overlap. If you have standing, I don't expect I'm going to dismiss the 93A claim. But keep going.

03:24

MR. CORNFELD: Okay. We have -- as your Honor pointed out, we have literature in the complaint. Judge Wolfson in the *Cottrell* case gave us leave to amend, and we did amend that complaint. And we emphasized the specific literature where

scientists have said, peer-reviewed literature undisputed in any publication, where they've said that if the drops were smaller, prices would be lower.

THE COURT: So actually, let me -- you're in the *Cottrell* case, too?

MR. CORNFELD: Yes, yes, your Honor.

THE COURT: That's another eyedrop case?

MR. CORNFELD: It's actually the exact same factual claim but involving different states, involving other states.

03:25 THE COURT: Why shouldn't there be one case, or why shouldn't these cases be consolidated?

MR. CORNFELD: For example, convening in MDL, nobody's asked for an MDL in any of the cases your Honor.

THE COURT: But here you didn't just bring a case -- I mean, this is a digression, but it has some practical significance. You don't bring your claim just under Massachusetts law. You bring it under the law of many states, other states.

MR. CORNFELD: Yes, your Honor.

03:26 THE COURT: Could those claims have been brought in New Jersey?

MR. CORNFELD: Actually, the first case was brought in the Southern District of Illinois. There are three cases in the United States now. And could we have combined them all? I don't see a reason why we couldn't have, your Honor. Nobody --

all of these, except for Akorn, which is a defendant here and is not a defendant in the Southern District of Illinois, all of the parties are the same in all three cases.

THE COURT: Many of you have children you want to put through college.

MR. CORNFELD: I would like to have these cases resolved as soon as possible, actually, your Honor.

THE COURT: So would they. They'd like to dismiss them.

03:26 MR. CORNFELD: Anyway, I understand what you're saying. The first case was in the Southern District of Illinois. I don't know where -- if somebody asked for an MDL, if the MDL panel would convene one and where it would go.

THE COURT: But is there more you'd like to say on standing?

MR. CORNFELD: No. I mean, I have the literature that we cited that shows -- I could show it to you here if you're interested, but it's just literature, one paper after another.

THE COURT: The literature shows --

03:27 MR. CORNFELD: That -- excuse me. I'm sorry, your Honor.

THE COURT: Go ahead. I'm familiar with the allegations of the complaint.

MR. CORNFELD: It supports our allegations.

THE COURT: Why don't you repeat them.

MR. CORNFELD: Okay. If the drops had been smaller, then the cost would be less for patients.

THE COURT: But basically you're saying the literature shows that anything over 15 or 16 microliters has no medicinal value. Lots of it doesn't even get into the body because it can't be absorbed. And if that's all you had, it would be a reasonable inference to conclude for motion to dismiss purposes that they're designing their droppers to dispense twice as much so they can get people to buy twice as much as they really need, but you have something else, too. You have a reported statement from an executive of one of the defendants saying, Yes, that's our motive.

MR. CORNFELD: That's correct, your Honor; that is correct. We have literature that supports both points, that anything above 15 or 16 microliters is wasted, doesn't provide any benefit, and literature that says -- including by these companies but also by independent people, that says if the drops were smaller, the cost to patients would be less. And we have the statement by Alcon's executives.

03:28 03:29

THE COURT: I bet you'd like to respond to this.

MS. BLADOW: If you don't mind, your Honor.

THE COURT: That's okay. You've been waiting a long time.

MS. BLADOW: I really would like to respond because I do think the Article III issue is a critical one here and

obviously always one that's critical for any Article III court.

THE COURT: I write that and say that often. Basically if I don't have jurisdiction or they don't have standing, there's no case or controversy. That's a constitutional issue.

MS. BLADOW: Absolutely, your Honor, and it's one that should not be taken lightly, and it's one that should not require any stretches, any conjecture, any hypothetical situation. But that's what we have here.

03:29 I'll start with the Alcon statement and the literature that Mr. Cornfeld is talking about. There's nothing he can cite to, your Honor, that says that these defendants are required or intend to make more money by having larger drop volumes or are required to charge less for a bottle that contains less liquid.

I mean, you know, you have to think of the big picture here. Particularly after -- these companies have been making these drops for years. They're all FDA approved. They went through the process already of spending a lot of time and money

03:30 to put these products out on the market. And now the assumption is or quote, unquote, "reasonable inference" that your Honor is suggesting you might draw is that just because one employee at one of the defendants said that this might be a motive? I mean, that says nothing about --

THE COURT: When I rule on this, you'll hear what I

say, and that's not what I said. I said it would be a reasonable inference even if you didn't have that statement but that statement is fairly powerful. And of course standing can be reviewed at summary judgment. If there are disputed material facts, they can be decided at trial.

MS. BLADOW: Absolutely, your Honor, and I agree with that. And I certainly believe that if your Honor rules against the defendants we would re-raise it as soon as we can because I think it would be a mistake.

03:31 On the *Nexium* and the *Solodyn* cases, those are antitrust cases. Those are cases where there was, by definition, based on the claim, an artificially inflated price. So that's how they got to the artificially inflated price that actually showed injury in those claims. Here we don't have that. I mean, here, even if your Honor is inclined to look at the 93A claim --

THE COURT: Of course I'm inclined to look at it. They made a claim.

MS. BLADOW: You have a -- I mean whether or not 03:31 plaintiffs have specifically adequately alleged that claim. You have a situation where this product -- you can't possibly determine that a product, putting a product out on the market that has been FDA approved is an unfair business practice.

THE COURT: Here. I don't need to hear anymore. We've got some complicated issues. That's wrong. You can mark

it a perfectly safe, approved thing in a false and misleading way, and that's essentially the allegation. I haven't discerned and I haven't heard you say that the FDA or somebody said you have to dispense at least 30 microliters to have an efficacious dosage.

MS. BLADOW: My point --

THE COURT: I've heard enough. I've heard enough.

MS. BLADOW: Thank you, your Honor.

THE COURT: Thank you very much.

03:32 All right. The defendants' motion to dismiss for lack of standing is hereby denied based on economic injury in fact. The plaintiffs have confirmed that they're not relying on or alleging physical injury that would create or contribute to creating standing.

Essentially, in this case, plaintiffs allege that the defendants packaged eyedrops in droppers in a way that dispenses more than necessary and more than the eye can absorb to assure that some will be wasted and the consumers will have to buy more and the defendants will make more money.

03:33 Among other things, plaintiffs allege that there are scientific studies that support their theory that more than 15 microliters is not needed for an effective dose and the 30 or 45 microliters that various defendants' droppers dispense are materially more than the eye could absorb.

The allegations in the complaint include in paragraph

75 that the lead researcher in a published study was told by Alcon, defendant Alcon, marketing executives that the company would not change the drop size because, quote, "It would mean that patients would be able to use the bottles longer and Alcon would therefore sell less product and make less money."

Paragraphs 66, 71, 72, 78, there are also studies cited that essentially conclude that 16-microliter drops are as effective as larger drops. It's permissible to consider these studies because they were referenced in the amended complaint. That's *Rivera*, 575 F.3d 10, 15.

Count 1 of the amended complaint alleges a violation of Massachusetts General Law Chapter 93A. Chapter 93A prohibits unfair and deceptive acts or practices. As the First Circuit has noted, quoting the Massachusetts Supreme Judicial Court, "Conduct is unfair or deceptive if it is within at least the penumbra of some common-law, statutory, or other established concept of unfairness or immoral, unethical, oppressive or unscrupulous." That's *Cummings*, 244 F.3d 16, 25, quoting the Supreme Judicial Court decision in *PMP Associates*, 366 Mass. 593, or 321 N.E.2d 915, 917.

The plaintiffs essentially allege that they and the class they seek to represent have been unfairly overcharged for prescription eyedrops. Theories of unfair overcharging have been recognized by district courts in this district, including in *Cape Cod Commercial Linen Service*, 2014 WL 268678 at page 8,

which denied a motion to dismiss a Chapter 93A case alleging unfair overcharges, and *Moniz*, 484 F. Supp.2d 228, 231. Therefore the defendants generally alleged a plausible Chapter 93A claim.

Plaintiffs have also adequately alleged requirements for standing based on economic injury in fact. There are three constitutional requirements for plaintiffs to have standing: Injury in fact, causation, redressibility. Those requirements were set out by the Supreme Court in *Lujan*, 504 U.S. 555 at 560-61. In *Lujan* the Supreme Court also wrote, "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we presume that general allegations embrace those specific facts that are necessary to support the claim." The Supreme Court -- the First Circuit construes this requirement broadly, stating in *CoxCom*, 536 F.3d 101, 107, "Plaintiffs seeking to demonstrate injury-in-fact need not establish a particularly damaging injury; they need only show that they were directly affected by the conduct complained of, and therefore have a personal stake in the suit."

Regarding, the First Circuit in *Adams v. Watson*, 10 F.3d 915, 918 has stated that, "The injury-in-fact inquiry is 'very generous' and that it 'serves to distinguish a person with a direct stake in the outcome of litigation, even though small, from a person with a mere interest in the problem,'" end

quote.

The plaintiffs here have alleged a plausible claim that they've overpaid for the defendants' eyedrops. They have done that in paragraphs 11 and 90 of the amended complaint. Most specifically, as I indicated in the course of the argument, in paragraph 65, they describe a study published in the American Journal of Ophthalmology, which quotes -- they allege that that study showed Alcon refused to sell its product with 15 microliter drops because, as the company's top
03:41 marketing executives told the study's senior author, Dr. Alan Robin of John Hopkins School of Medicine, it would mean that patients would be able to use the bottles longer and Alcon would therefore sell less product and make less money.

Essentially, as the First Circuit said -- although the theory of the cause of action was different in *In Re: Pharmaceuticals*, 582 F.3d 156 at 190-191, "Overpayment is a cognizable form of injury for standing purposes." As I noted in the course of the argument, *Dominguez*, on which the defendants rely in part, is a case that was decided by the D.C.
03:43 Circuit on a motion for summary judgment. What this reflects is the fact that whether the defendants would charge the same for smaller bottles or less is a factual issue, one that would need to be addressed on a motion for summary judgment or at trial. But to me, it is plausible that the defendants would charge less for smaller bottles or the same size bottles that

would last longer if they were dispensing 15 microliter drops and that the motive for dispensing drops that are two or three times that large is to make more money.

I've also considered the *Cottrell* case. It discusses the Third Circuit standard that is not the same as or comparable to the standing under Mass. General Law Chapter 93A. So for that reason, the motion to dismiss based on standing is denied.

Then next in my outline is the motion to dismiss based on impossibility preemption. This is an affirmative defense, and I noted earlier, I think, that again, it's important to try to assure that we have in mind -- everybody has in mind the proper standard. What I understand the proper standard to be when defendants rely on an affirmative defense in a motion to dismiss is as stated by the First Circuit in *Blackstone Realty*, 244 F.3d 193, 197. The First Circuit said in part, "It is well established that affirmative defenses, such as the failure" -- in that case -- "of a contract sued upon to satisfy the statute of frauds may be raised in a motion to dismiss an action for failure to state a claim. However, it is equally well-settled that for dismissal to be allowed on the basis of an affirmative defense, the facts establishing the defense must be clear on the face of plaintiff's pleadings. Furthermore, review of the complaint, together with any other documents appropriately considered under Federal Rule of Civil Procedure 12(b)(6) must

leave no doubt that the plaintiff's action is barred by the asserted defense."

So that's my understanding of the standard. My understanding of the general standard of impossibility is as stated in *PLIVA*, 131 S.Ct. 2567, 2579 where the Supreme Court wrote, "The question for impossibility is whether the private party could independently do what state law requires." And in *Wyeth*, 555 U.S. 555 at 573, this was characterized as a demanding defense.

03:47 So I am interested in hearing from you on this one. Although, without going into the specifics, it's my tentative view that this motion to dismiss also is not meritorious, that if the statute of limitations on something is three years, the plaintiff alleges that the injury occurred in -- the case is brought in 2014, it's clear that from the face of the complaint that the statute of limitation bars the action. At the moment, it's not -- I know this is more complicated. Something that's complicated can also be clearer when you understand it, but at the moment, it doesn't seem to me that the affirmative defense 03:48 is comparably clear. But who would like to speak to this for the defendants?

MS. JACXSENS: Your Honor, I'm Christiana Jacxsens with Greenberg Traurig. I represent Sandoz, the Alcon defendants and Falcon. And as I described earlier, I'm speaking on this topic on behalf of the defendants. And I'm

sure people will send me some notes if there's things that they want to chime into.

But we do believe that this is very clear on the face of the complaint. And I'm going to address first, and I think your Honor pointed out that we have two different preemption arguments here. We have one, the impossibility preemption argument. And that applies to both the brand and the generics. And then we have a separate motion that applies just to the generics. And is your question, your Honor, would you like me 03:49 to address the one that applies to both brand and generics?

THE COURT: Yes. That's what I'm interested in focusing on now and then maybe we can go to generics.

MS. JACXSENS: It is clear to us on the complaint that these claims are preempted. So just a few important background points that I want to point out. On its face plaintiffs are asking for the defendants to cut the dose in half. That requires not just cutting the dose in half in that change and administering then half of the active ingredients. It also requires a redesign of what's called the container closure 03:49 system.

THE COURT: Could I just ask a question? It may have to be answered by the plaintiffs. I thought that at least part -- you say they're seeking to have you change the dropper --

MS. JACXSENS: Yes.

THE COURT: -- seeking to have you pay them money. This is the way I interpret it, and maybe there's a reason it hasn't been briefed this way. I want to be as transparent as possible so this argument can be as helpful as possible.

I thought they were arguing that it was designed originally before FDA approval was sought and obtained, and it was designed to -- the droppers were designed to dispense 30 or 45 microliters, it says in paragraph 90, as part of a scheme to increase profits by selling more products than consumers want or need, and that was the theory. So it's something of a -- something that was designed to essentially deceive consumers into thinking they needed eyedrops of 30 to 45 microliters.

And that goes even back before the approval of the FDA. Is that part of the claim, or it's not part of the claim and there's a reason it's not part of the claim?

MR. CORNFELD: Your Honor, I'm not sure I understand your question. What are you asking, is what not part of the claim?

THE COURT: That essentially the original design of the stoppers was to, you know, waste part of the medication and make more money as a result.

MR. CORNFELD: Yes. Yes, your Honor.

THE COURT: And that -- I'm sorry. Go ahead.

MR. CORNFELD: And they've kept the droppers making drops that are too large.

How this works on preemption, I believe, is they are raising the defense that for them to change the drop size would require them to do things that would result in the necessity to obtain prior approval from the FDA.

THE COURT: I don't even know why they would need to change it. They would just need to pay you.

MR. CORNFELD: Well, our claim is for damages for the amount that we -- yes, for the amount that our clients -- just as your Honor just explained in the ruling -- the amount that our clients spent on medication that could not be provided -- could not give them a therapeutic benefit.

MS. JACXSENS: Your Honor, if I may address this point?

THE COURT: Of course.

MS. JACXSENS: That isn't clear from his complaint. What's clear from his complaint is that at this point in time they are asking the defendants to redesign a container closure system. It's a container closure system that has never been approved by the FDA.

THE COURT: What makes that clear? Is that one of the remedies?

MS. JACXSENS: Let me pull out the complaint.

THE COURT: I suppose it's paragraph 6, prayer for relief on page 74.

MS. JACXSENS: Correct.

THE COURT: "Awarding declaratory and injunctive relief as permitted by law or equity including a preliminary and permanent injunction enjoining defendants from continuing the unlawful practices as set forth herein." That's 6. 3, 4 and 5 ask for money damages.

MS. JACXSENS: That's correct, your Honor. So they're saying you need to take these products off the market, and you need to redesign them if you want to get them back on the market again. That's part of the relief that they're
03:54 requesting, in addition to the monetary relief. And that is part of why all these claims are preempted. In order -- just to give you a little bit of background about ophthalmic products, these are special products. So these are products in which you have a sterile drug, and that's important when you're dealing with the eye. It has to be sterile. And you have a specific container closure system that's designed to protect the sterility of the product. You don't want to have your eye become infected with your treatment.

So the FDA looks at this as a system, as one product.
03:55 If you're going to make changes to it, the FDA looks at that as a whole, both as to changes to the dose or the ingredients but also to the container closure system. And in binding FDA guidance, it has specifically said, this is an important consideration, if you are going to change the container closure system for products that are sterile, it does require approval

by the FDA.

THE COURT: But the FDA said that in 2014, I think; is that right?

MS. JACXSENS: Yes. Well, which --

THE COURT: I thought this was your argument, that changing the volume dispensed by the dropper would be a major change, and in 2014, the FDA issued guidance that says, "Changes that may affect the control or modify the release, metering or other characteristics, e.g., particle size of the dose delivered to the patient, including the addition or deletion of a code imprint, is considered a major change." Is that 21 CFR section 320.70? Is that what you were talking about?

MS. JACXSENS: I'm talking about 21 CFR section 314.70, the version I'm looking at was effective December 22, 2008.

THE COURT: Could I have that, please, 2008.

MS. JACXSENS: Then I'm also looking an FDA guidance document.

THE COURT: Hold on just one second. What part of 314.70?

MS. JACXSENS: Section B changes requiring supplement submission and approval prior to distribution of the product made using the change.

THE COURT: Hold on a second.

MS. JACXSENS: Okay.

THE COURT: That one says that "A supplement must be submitted for any change to the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product."

MS. JACXSENS: That's right. And if you look at subsection 2, it gives examples of those types of changes. This section B relates to what's called major changes. And under (b)(ii), if you look at subsection part 3.

THE COURT: Hold on a second. (b)(ii), okay.

MS. JACXSENS: So the first subsection is also applicable, the subsection i, which says, "Changes to the qualitative or quantitative formulation of the drug product, including inactive ingredients," that's what gets to the change in the dose or change in the amount of the active ingredient delivered. But then if you also look at subsection iii, "Changes that may affect drug substance or drug product sterility assurance," that's what we're talking about with the container closure systems. And if you look at subsection iv -- sorry. I'm skipping ahead a little bit -- "Changes in a drug product container closure system that controls the product delivered to the patient."

THE COURT: Is that what a dropper is?

MS. JACXSENS: That's what the dropper is. That's further described, your Honor, in a guidance that the FDA issued in April of 2004.

THE COURT: Not 2004.

MS. JACXSENS: It was back in 2004.

THE COURT: Isn't this 2008?

MS. JACXSENS: I believe that this version of 21 CFR 314.70 was from 2008. And I have to look back to see when the original one was, but this subsection dates back to -- well, it has citations back to 1974, so I need to see what the changes were. But this guidance, which dates back to 2004 --

THE COURT: I'm sorry. What's the citation to that one?

MS. JACXSENS: This one, the citation is 2004 WL, 3199016 issued April 2004. It's called, "Guidance For the Industry, Changes to an Approved NDA or ANDA."

On the WL citation page star 16, for the version on the FDA website, which would be page 20, it has a section, section 9, called "Container Closure System." And your Honor, I have an extra copy. Would that be helpful?

THE COURT: Yes. I think that would be good.

MS. JACXSENS: Okay. I'm going to go ahead and give you this one, too.

MR. STRAUSS: May I approach, your Honor?

THE COURT: Yes.

MR. STRAUSS: This is two copies of that and two copies of that.

THE COURT: All right. Where do you want to start?

MS. JACXSENS: I'm looking at page 16.

THE COURT: Of what?

MS. JACXSENS: Of the document that's titled "Guidance For Industry Changes to Approved NDA or ANDA."

THE COURT: What page would you like me to look at?

04:02 MS. JACXSENS: Page 16, section 9, called "Container Closure System."

THE COURT: Okay.

MS. JACXSENS: Then part B has "Major Changes, Prior Approval Supplement." And then if you look at -- so at the bottom it says -- it starts talking about these are examples of changes considered to have substantial potential to have an adverse effect on the identity, strength, quality, purity or potency of a drug product. So that's how that fits into the 314.70 standard.

04:02 And if you look at subsection iii, the example that it gives is, "A change in the primary packaging components for any drug product when the primary packaging components control the dose delivered to the patient," and then subsection iv is, "For sterile drug products," which the ophthalmic products are, "any change that may affect drug product sterility assurance such

as," and if you look at the sixth bullet point, it says, "Changes in the size and/or shape of a container for a sterile drug product."

THE COURT: Sorry. Where is that?

MS. JACXSENS: Part section number 4, this is on page 17, and it's the one, two, three, four, five, the sixth bullet point right above number 5.

THE COURT: Okay.

MS. JACXSENS: What this guidance document is saying is that it's important to the FDA. It's considered a major change. If you're going to make a change to a system that holds a sterile drug like ophthalmic products are, then the FDA considers that to be a major change that can have substantial potential to an adverse effect on the product that could relate to the safety or effectiveness of the drug and it wants to have the ability to give the prior approval before that's marketed.

Here, in order to have a drop size that's 16 microliters -- your Honor, this is currently one of the drug products at issue. In order to change that dropper tip so that it releases at 16 microliters -- this is about 34, say. To change it to administer at half, you're talking about changing the whole design because it would have to be very narrow, as you can imagine, to have a little hole that's even smaller than this that would distribute a drop that size would be very narrow. So you're talking about something that has to be more

pointed. And that whole design would affect not only whether that bottle can maintain the sterility of the product but also the safety of this container closure system, which is something that the FDA also considers. Here, when you're talking about patients with glaucoma, which these drugs are used to treat, you are talking about patients where that would be a concern for the FDA.

THE COURT: Hold on just one second.

Let me ask you this because I believe the plaintiffs point to it. When I said "2014," I think I was remembering -- I mean misremembering what the FDA did in 2004.

What is the meaning of the following? I think it's 69 FR 18745. The FDA wrote, "For sterile drug substances, the effect of changes in the size and/or shape of the container closure system is considered by the FDA to be of lower risk because of the differences in procedures, sterilizing drug substances and drug products, but the risk is still higher than for non-sterile products. Therefore, the FDA declines to specify in the regulations that these changes can be submitted in a changes-being-effected supplement."

It appears that it left -- the plaintiff argues, left the issue open for later interpretive guidance. It also wrote, "Through guidance, the FDA may identify certain container closure system changes for sterile drug products that can be reported other than by submission of a prior approval

supplement. Furthermore, an applicant could submit a comparability protocol that would allow it to implement post-approval changes in sterile container closure systems without a prior approval supplement."

What's the meaning or import of that?

MS. JACXSENS: I think what the FDA is saying there, your Honor, is that, since there are three levels of changes, the moderate change, which is what plaintiffs are suggesting defendants could do here, under what's called a CBE 30 would apply, which means the defendants could submit it to the FDA, basically give notice and then later on the FDA would approve.

THE COURT: You say they could make the change, give notice, pending approval?

MS. JACXSENS: With the CBE 30 --

THE COURT: I'm sorry. Go ahead.

MS. JACXSENS: Yes, exactly, but you can still go ahead and market it; you would just give notice.

THE COURT: Without the prior approval?

MS. JACXSENS: Without the prior approval. But what that is saying is there are some changes that can be made that may fall into that category and the FDA would let the parties know, if that's the case, that it would fall under that category.

What this guidance makes clear is that they're saying it is a major change if it's a change in the size and/or shape

of a container for a sterile drug product. So the FDA did give guidance on that fact that would affect the container closure system here in addition to the fact that it would also be considered --

THE COURT: So let me just see if I get this. You're saying that the FDA recognizes there may be some changes that could be made to a closure --

MS. JACXSENS: System, yes.

THE COURT: -- system without prior approval, but those changes don't include the size and shape of a container for a sterile drug product?

MS. JACXSENS: That's how I read that, your Honor. That's correct.

THE COURT: Go ahead.

MR. CORNFELD: May I respond to that, your Honor?

THE COURT: I think it would be helpful if I -- just on this narrow point?

MR. CORNFELD: Just on this narrow point.

THE COURT: Go ahead.

MR. CORNFELD: If you would look at the guidance document that counsel gave you, Guidance For Industry Changes to an Approved NDA or ANDA, on page 17, the same one that counsel has been reading from, that said that a major change --

THE COURT: Where are you looking?

MR. CORNFELD: If you look at page 17.

THE COURT: Right. Where on 17?

MR. CORNFELD: First let's look at the last bullet point. That's the one counsel read to you. It says that, "A major change would be changes in the size and/or shape of a container for a sterile drug product," and if you go up and look at number 4, above that, that describes what they're talking about. They're talking about, "For sterile drug products, any change that may affect drug product sterility assurance." So if you change the size and/or shape, and it affects the sterility assurance, that is a major change. Now, let's look down --

THE COURT: But you're saying what you're advocating wouldn't affect drug product sterility?

MR. CORNFELD: We don't know. But let me also -- I should say we don't know on this record. In paragraph C, just below on page 17, where they talk about moderate changes, those would be something that they could get on changes -- on the changes-being-effected or CBE supplement and would not require prior approval, if you look at paragraph B, or line B -- actually, let's start right after star 17. "The following are examples of changes considered to have a moderate potential to have an adverse effect." Line B says, "Changes in the size or shape of a container for a sterile drug substance."

So what they're saying here is that that's the same thing. If you change the size or shape, if you change it in a

way that would affect sterility assurance that might let germs get in or what have you, then you have to have prior approval. But if it's not going to affect sterility assurance, you don't need prior approval.

And the question will be, once we get in discovery, would a change -- we know they approved -- we submitted these in our briefs and in the complaint. We know from publicly available documents the FDA has approved changes in the size and shape of container closure systems on a CBE 30. The question here will be would this change that would result in a smaller drop size affect sterility assurance. That is a factual issue. That's not appropriate for decision on a motion to dismiss in our view, your Honor.

MS. JACXSENS: Your Honor, if I may address that, because I think that there is some misunderstanding from what plaintiffs' counsel pointed out. The bullet point that I point out refers to a sterile drug product. So that's the whole product. The bullet point that the plaintiffs point out to is a sterile drug substance. If you look at -- this is 21 CFR 200.50, called "Ophthalmic Preparations and Dispensers."

THE COURT: Do you have a copy of that for me?

MS. JACXSENS: You know, I don't.

MR. CORNFELD: What was that again?

MS. JACXSENS: 21 CFR 200.50. It's referenced in our brief. Should I put it on the Elmo perhaps?

THE COURT: Sure.

MS. JACXSENS: There's the citation, your Honor, 21 CFR 200.50. The highlighting is mine. It says, "Informed medical opinion is in agreement that all preparations offered or intended for ophthalmic use" --

THE COURT: Don't go too fast.

MS. JACXSENS: Okay. Sorry.

THE COURT: Go ahead.

MS. JACXSENS: -- "including preparations for cleansing the eyes, should be sterile. It is further evident that such preparations purport to be of such purity and quality as to be suitable for safe use in the eye."

If you look down at subsection 3 then, it says, "The containers of ophthalmic preparations shall be sterile at the time of filling and closing." So while this guidance related to container closure systems may apply to other drug products, the FDA has been very clear that for an ophthalmic product, the container closure system must be sterile, must protect the sterility. That's further supported in the other guidance that I handed to your Honor.

THE COURT: Let me go back to this one.

MS. JACXSENS: Okay.

THE COURT: The difference between moderate and major changes. It's a major change if it's a change in the size and/or shape of a container for its sterile drug product. It's

a moderate change if it's changes in the size or shape of a container for a sterile drug substance. Is there something that explains the distinction between the product and the substance?

MS. JACXSENS: There is, and I'm looking to my co-counsel because I think they have the citation. It is defined, and the substance is considered to be the raw ingredient, so not the product that would actually be delivered to the patient, versus the product, which is the ophthalmic product. This is further made clear, your Honor, if I may, in this other guidance that I think may be helpful. And this guidance is called "Guidance For the Industry Container Closure Systems For Packaging Human Drugs." It was issued May 1999. The citation is --

THE COURT: I'm not saying seeing that on the screen.

MS. JACXSENS: Sorry. Here we go. Let me go to the front page. Sorry. Here we go. 1999 WL 3393528. "Further guidance" --

THE COURT: What page are you on?

MS. JACXSENS: I'm looking at page 18. So first I just wanted to show your Honor this page, which is Table 1, page 5. It has examples of packaging concerns for common classes of drug products. Where there's a likelihood of a component dosage form interaction, and it lists ophthalmic solutions and suspensions as high. Then your Honor, look at --

okay. This is section E, "Drug Products."

THE COURT: What page?

MS. JACXSENS: Page 18. Sorry. This is 18. "Drug Products For Injection and Ophthalmic Drug Products." So it explains that these ophthalmic drug products are commonly solutions or emulsions or suspensions. And actually, your Honor, I do have the citation for you about the substance versus product.

THE COURT: We'll come back to that.

04:19 MS. JACXSENS: All right. Sorry. So on this page it explains why -- it says that, "Although the risk factors associated with ophthalmics are generally considered to be lower than for injectables, any potential for causing harm to the eyes demands caution." That's explaining why it's considered to be, when you're looking at the potential for contaminants due to -- it says, "Any contaminant present as a result of contact with the packaging component or due to the package system's failure to provide adequate protection can be rapidly and completely introduced into the patient's general

04:20 circulation." That's the case with ophthalmic products, and it goes on to explain down here on page 19, "These drug products are usually solutions marked in a bottle with a dropper, sometimes referred to a drop-tainer.

THE COURT: Okay. Let me look at this. Okay. Two things before you tell me about the distinction. I'm going to

have a question for you. But where do I find a distinction between the product and substance?

MS. JACXSENS: I have it for you here on an iPhone. It's 21 CFR 314.3. I'm not sure if I have that.

THE COURT: I don't have that.

MS. JACXSENS: Okay. I'm sorry, your Honor. I'm happy to e-mail a copy of the citation if that would help.

THE COURT: It's my intention to decide this this afternoon if I can. So tell me --

04:22 MS. JACXSENS: So it says, "A drug product is basically a product in finished dosage form, the finished form, the form that goes to the patient. For example a tablet, capsule, solution that contains the drug substance generally but not necessarily in association with one or more ingredients." So it's the finished dosage form.

THE COURT: And the product is --

MS. JACXSENS: Versus the substance, the substance which is in that moderate category versus the finished form which is in the major category. "The substance is an active 04:22 ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure or mitigation, but it does not include intermediates used in the synthesis of such ingredients." So it's not the finished form. It is what would be approved if it were going to be combined or used in combination to become the finished form.

THE COURT: Let me ask you this series of questions. The plaintiffs point me to 69 FR 18728-01, which is "Supplements and Other Changes to an Approved Application." I believe I'm told that this is essentially commentary on the binding guidance that you've been pointing me to.

MS. JACXSENS: I think that's -- may I go get that copy? I have a copy it at the desk.

THE COURT: Yes.

MS. JACXSENS: Okay. I think I have it here in front of me.

THE COURT: All right. It says, in part, in the second to last paragraph, second sentence --

MS. JACXSENS: Sorry. What page was that your Honor?

THE COURT: Sorry. 39, the paragraph that starts, "As stated in the June 1999 proposal."

MS. JACXSENS: I'm on page 39.

THE COURT: Do you see the last full paragraph starts, "As stated in the June 1999 proposal"?

MS. JACXSENS: I'm sorry, your Honor. If you want to continue to ask your question, hopefully I can find it while you're --

THE COURT: Maybe we have a different version. Are you looking at the "Supplements and Other Changes to an Approved Application"?

MS. JACXSENS: Yes, 69 FR, and then are you looking at

18739?

THE COURT: No. I'm looking at 18728.

MS. JACXSENS: 18728, okay.

THE COURT: Looking at the page, it says 39 in the lower right --

MS. JACXSENS: I see. Wait. My version isn't numbered at the bottom. Okay. I see what you're saying.

THE COURT: Do you have that paragraph? I might give it to you to put up for everybody. Here. Why don't you put it up so we're all looking at the same thing.

MS. JACXSENS: Okay.

THE COURT: We have to go down to the bottom of the page. Do you see where I put that checkmark?

MS. JACXSENS: Yeah. Okay, okay. I see.

THE COURT: So was this document issued by the FDA after the binding guidance we've been talking about?

MS. JACXSENS: I believe it was issued before. I believe this is like the background information and the commentary to the proposed guidance that the FDA was looking to issue. And then the guidance document you and I were discussing is the final document. So this is where the FDA is reporting in the FR the commentary that it received on the draft.

THE COURT: But what's the date of that document?

MS. JACXSENS: The date of the guidance just says

"Issued April 2004."

THE COURT: And what's the date of the binding guidance that you --

MS. JACXSENS: That's all it says, "Issued April 2004."

THE COURT: Well, they're both issued April 2004.

MS. JACXSENS: Right. It's my understanding that this FR was how the FDA was publishing here's our draft guidance, we're seeking commentary.

04:28 THE COURT: Well, that doesn't sound right to me.

MS. JACXSENS: Okay.

THE COURT: In my experience, the United States government doesn't issue a request for commentary and in the same month issue the regulations. It appears to me it may have been issued simultaneously or the interpretive guidance might have been issued afterwards.

MR. DeMOURA: Your Honor, it says on the front page of the document that you want her to read from that this is the final rule. If you look at the first page, it says --

04:29 THE COURT: I don't --

MR. DeMOURA: The first page --

MR. CORNFELD: The first page of the FR.

THE COURT: We may have these in different forms. I've had more coherent presentations made to me with charts and things, frankly. I mean, isn't this -- what I just gave

counsel is something that was cited by the plaintiff.

MR. DeMOURA: Right. It is the final rule. We attached it to our materials in the form, I think it's document 60-4.

MS. JACXSENS: I do have an understanding. This is the final rule that --

THE COURT: What is it? I can't see what you're --

MS. JACXSENS: I'm sorry. This document that you were looking at, this one that's dated April 8, 2004, the FR printout, it relates to different CFR parts that include section 314. That was the first regulation that we were talking about. And so this is where the FDA is setting out and addressing the comments related to different of the CFR regulations, including the 314 one that talks about what is a major change.

THE COURT: So the document I gave you came out in conjunction with the finding, with the regulations; is that correct?

MS. JACXSENS: It came out in relationship to this, the 314, but it came out at the same time as this guidance that the FDA issued, that's correct, at the same time.

THE COURT: I'm not clear on this and now you have my documents. 21 CFR 314.70.

MS. JACXSENS: May I approach, your Honor? I'm happy to give this back to you. I'm now following along.

MR. CORNFELD: Actually, I have an extra copy for his Honor.

MS. JACXSENS: It's okay. I'm happy to give that back. I have that copy, so I know where we are now.

MR. CORNFELD: Okay.

THE COURT: But I don't have something that looks like what you've got on the screen in front of me, although it's probably -- I was reading it in different forms.

So now I have 314.70. How does it relate to what is in 69 FR 18728 that I gave you?

MS. JACXSENS: So if you look at starting on page --

THE COURT: Just tell me how it relates.

MS. JACXSENS: This is where the FDA is setting out what this final regulation is going to be.

THE COURT: What it's going to be or what it is?

MS. JACXSENS: What it is, but then this is the actual regulation, how it appears in the CFR, and these are the comments.

THE COURT: Do you think I can see -- I don't mean to be abrupt with you. You're holding it up like this. It's not on --

MS. JACXSENS: I apologize, your Honor. I'm sorry.

THE COURT: I have no idea what you're talking about. That's 314.70, right?

MS. JACXSENS: Yes.

THE COURT: And I want to know how -- that regulation was promulgated on what date?

MS. JACXSENS: The printout that I have says this version was effective September 22, 2008, but according to -- but there was an earlier version of this regulation in place, and that was addressed in this 69 CFR from April 8, 2004.

THE COURT: Okay. That's what I gave you.

MS. JACXSENS: Yes.

THE COURT: Okay. And then in that document, it says, "Through guidance, FDA may have identified certain container closure system changes for sterile drug products that can be reported other than by submission of a prior approval supplement," right?

MS. JACXSENS: Right. Other than by prior approval.

THE COURT: They said that in 2004?

MS. JACXSENS: Yes, your Honor.

THE COURT: It says, "They may identify." The plaintiffs will have to answer this, too. Did they ever identify?

MS. JACXSENS: No, your Honor. We have not seen any guidances that say for a sterile product that you do not have to do the major change.

THE COURT: Then the plaintiffs identify three circumstances where some of the defendants purportedly made changes to the container or container closure systems without

FDA pre-approval, instead relying on the CBE regulation, and the FDA approved the changes. What is your response to that?

MS. JACXSENS: That goes to the fact that there are some changes that can be made to a container closure system that may not affect the sterility of the product. So if they're changing the packaging that goes around the bottle, there are changes that can be made. None of those changes that plaintiffs cite to relate to changing the dispenser tip to issue a smaller drop size.

04:35 THE COURT: Well, which is the document that makes the distinction between sterile products and sterile substances?

MS. JACXSENS: That is -- this is the April 2004 guidance.

THE COURT: How do I know that none of those changes related to size or shape of the sterile drug product, and how can I deal with those documents which aren't referred to in the complaint on a motion to dismiss?

MS. JACXSENS: I can pull up those documents themselves, your Honor. But if you read the general context of

04:37 the letter, you can tell that they're not the same kind of changes that plaintiffs are requesting here.

THE COURT: How can I consider -- I've got to remind myself to go back to the proper standard. There are only certain documents that I can properly consider on a motion to dismiss. Maybe I can't consider those documents at all. But

why don't you go ahead. Then I want to hear from the plaintiffs.

MS. JACXSENS: Well, I would say, your Honor, first, we would dispute in terms of you considering them on the basis of a motion to dismiss. But if you were going to consider them, then the whole context needs to be looked at because on the face of those documents themselves, it's clear that the types of changes that were being requested don't fall into this category of making a major change like here.

04:38 On the face of plaintiffs' complaint -- and you know, your Honor, quite frankly, I'm sure we wouldn't be here today if the plaintiffs weren't asking for a major change to these drugs. They're asking for a major change, and that major change, the only way to go about making it is to drastically redesign the container closure system. In addition to the fact of that, you're having a major change now, that the amount of your ingredient is half, the active ingredient is half, the amount of your dose is half. And it's those doses and those amounts of the ingredients that were approved by the FDA. And

04:38 the FDA looked at all that in the context of the clinical trials that were submitted to them that showed that at this dose, at this size eyedrop, that this provided a therapeutic benefit, it was effective for the patient, and it was safe.

What we don't have with this major change is, it's asking the companies and telling them that you can just put

these products on the market, a container closure system that's never been approved by the FDA. You can just put it out there on the market, a drug at half the dose for patients with glaucoma who have trouble administering these doses to begin with. But it's asking the defendants to circumvent getting the FDA approval and putting the drugs on the market without the FDA blessing these major changes.

THE COURT: Which of the cases -- so in which of the cases, particularly the Supreme Court trilogy, supports your argument most strongly?

04:39

MS. JACXSENS: In *Bartlett*, your Honor, the Court said once a drug, whether generic or brand name, is approved, any change to the qualitative or quantitative formulation of the drug product, including inactive ingredients, is a major change.

THE COURT: It says it's a major change. And then what does it say about preemption?

MS. JACXSENS: The question of preemption --

THE COURT: I'm sorry. What page were you just reading off of?

04:40

MS. JACXSENS: It's 2471. It's in part quoting the section 21 CFR 314.70(b)(2)(i).

THE COURT: And where does it tell me what the implications of that are for preemption?

MS. JACXSENS: For preemption, well, I'd like to go

back to the *Mensing* decision, which had the standard that, "When a party cannot satisfy its state duties without the federal government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for preemption purposes."

THE COURT: What page is that? Excuse me just a minute.

MS. JACXSENS: It's page --

04:42 THE COURT: Hold on just a second.

MS. JACXSENS I'm sorry.

THE COURT: Sorry. What page in *Mensing*?

MS. JACXSENS: *Mensing*, it's starting at page 2580 to 2581. In *Bartlett* -- going back and forth, and I apologize. But in *Bartlett*, the Court at page 2479 says, "State law design defect claims that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or

04:43 labeling."

THE COURT: So it's your argument that the plaintiffs are seeking a change. If a change is a major change, it requires prior approval of the FDA; and if prior approval of the FDA is required, the claim is preempted?

MS. JACXSENS: Yes, your Honor.

THE COURT: Why don't I hear from the plaintiffs.

MS. JACXSENS: Can I provide one more citation for your Honor that was in our supplemental briefing? This is to the point that this holding goes both to the brand and the generics. I know we haven't talked about the generics and their duty of sameness; that's a different argument. But for the brand, there was a case, *Yates v. Ortho-McNeil*, 76 F.Supp.3d 686, that said a design defect claim against the brand is preempted.

04:45 THE COURT: Sorry. What page?

MS. JACXSENS: This is -- I need to go back to my -- I'm going to go back to the desk if that's all right, your Honor.

THE COURT: Okay.

MS. JACXSENS: The *Yates* decision, 76 F.Supp.3d 680.

THE COURT: I have a Lexis version I think you gave me. So what page is this version?

MS. JACXSENS: Lexis version is 2015 U.S. District Lexis 2838. We'd be looking at --

04:46 THE COURT: Actually, maybe this isn't. Maybe I have whatever you gave me. *Yates*, 76 F.Supp.3d 680. What page after 680?

MS. JACXSENS: The pin citation is at 687.

THE COURT: What's the language that I'm looking for?

MS. JACXSENS: Well, the Court says -- it talks about,

"The Court's discussion holding in *Wyeth* concerning the labeling does not apply to Mrs. Yates' design defect claims." It's right above the section on negligence. "Therefore, under *Bartlett* and *Amos*, the defendants are entitled to summary judgment on a design defect claim."

THE COURT: I'm looking at the section on negligence, which is on 688, 686. I guess I'm just not seeing what you're reading. Read it again, please.

MS. JACXSENS: Okay. I'll kind of start back. Well, the Court explains at 687 --

04:48

THE COURT: What I can't find in the version you gave me is the number 687. I can find 686 and 688. "Negligence" is on 688, so where is it relevant on part 4, negligence?

MS. JACXSENS: The conclusion and that language about that the Court's discussion holding in *Wyeth* does not apply is shortly above that of 688, discussion of negligence. It's in the paragraph that starts, "The issue in question does not concern the adequacy of Ortho" --

THE COURT: I have that.

04:49

MS. JACXSENS: Sorry. It may be the 686. Yes, your Honor. I'm sorry. The other -- if I may give your Honor two more citations?

THE COURT: No. I want to understand the implications of this right now. It took long enough to find it. You might as well tell me. So what?

MS. JACXSENS: So this is explaining, your Honor, that the *Bartlett* decision is not just limited to generic drugs, that it applies also to brand name drugs, and it applies specifically to issues related to a design issue in brand name drugs. And if you look at the *Thompson* decision --

THE COURT: Does it make any difference that this was a motion for summary judgment?

MS. JACXSENS: I don't think in the case of *Yates*, your Honor. I don't see that they've submitted where there's a reference to the evidence, that it would make a difference here in the *Yates* case. And then in the *Thompson* decision was a motion to dismiss. And that citation is 993 F.Supp.2d 1007. This is *Thompson v. Allergan*. These are the same allegations as here.

THE COURT: Let me get the case. What page?

MS. JACXSENS: The pin cite is 1014. The Court says, "In sum, the Court finds" --

THE COURT: This is going to work better if you let me find it.

MS. JACXSENS: I'm sorry, your Honor. I'm sorry.

THE COURT: Go ahead.

MS. JACXSENS: Where it says -- at 1014, above, it says, "The Court concludes that reducing the amount of medicine in each Restasis vial is a major change requiring prior FDA approval." If you go down further, the Court concludes, "In

sum, the Court finds that 21 CFR 314.70(b)(2)(i) made it impossible for defendants independently to comply with the state law duty alleged in plaintiff's complaint."

THE COURT: Okay. Let me hear from the plaintiff, please. But just a minute.

MR. CORNFELD: Your Honor, the issue here is whether they could make the change to the container closure system to reduce the drop size on a CBE 30. Because under *Wyeth v. Levine* -- or CBE 30 or less, under *Wyeth v. Levine*, then it's not preempted because they could do it giving the FDA notice.

So what we know is that from the facts we presented that came from a publicly available source, I think one of the exceptions you mentioned was, is a document that's not in the complaint, a public document, and these are FDA documents. We know that they changed the size or shape of the container.

THE COURT: How do we know that?

MR. CORNFELD: We know that because the FDA approved Allergan's request on a CBE 30 to change the Zymar container from 10 milliliters to 8 milliliters, containing the same amount in the bottle.

THE COURT: Have I been given these documents?

MR. CORNFELD: Yes, your Honor. They are exhibits to our briefing. Exhibit E, which is the letter from the FDA.

THE COURT: Just one second. Let me get the document. What's the number?

MR. CORNFELD: Exhibit E.
THE COURT: To what?
MR. CORNFELD: The document number? I'm sorry, your Honor.
THE COURT: What's the name and date of the document?
MR. CORNFELD: It's an FDA letter.
THE COURT: No. You've submitted it. What was it attached to?
MR. CORNFELD: We submitted it with our brief in response to the omnibus motion to dismiss.
MR. DeMOURA: That would have been document number 60, your Honor.
THE COURT: Can somebody give me a copy?
MR. CORNFELD: Yeah. I have it here.
THE COURT: It may have been lost in transit. I guess I have Exhibit E.
MR. CORNFELD: Also, your Honor, Exhibit F and Exhibit G.
THE COURT: I guess I need F and G.
MR. CORNFELD: All right, your Honor. Your Honor, may I approach?
THE COURT: Yes.
MR. CORNFELD: So your Honor, the issue --
THE COURT: What is Exhibit E? Tell me.
MR. CORNFELD: Exhibit E is a letter available on the

FDA's website to Allergan that approves a new bottle on the CBE 30. If you look at the paragraph that begins, "These changes being effected in 30 days." That's the third paragraph after "Dear Ms. Bancroft."

"These changes being effected in 30 days supplemental new drug applications provide for a change in the fill size 5 milliliters of drug product in a 10 milliliter bottle and corresponding labeling revision. We completed our review of these applications as amended. These applications are approved effective on the date of this letter." And the date of the letter is June 20, 2005.

THE COURT: Let's see.

MR. CORNFELD: That's on the last page, your Honor.

THE COURT: It's on where?

MR. CORNFELD: On the last page. Do you see Linda Ng, and then 6/20/05?

THE COURT: Yes.

MR. CORNFELD: Okay. The other two exhibits are the labels from before that letter, so we see what was the size. And if you look at the last page, where it says, "How Supplied" -- I'm sorry, Exhibit F, the last page has a section called "How Supplied." This is the label -- it's also a public document on the FDA 's website. And it says, "5 milliliters in an 8 milliliter bottle," and we know the date of this label is 2003, so it predates what the FDA was approving.

And then the next exhibit is Exhibit G. And if you look, that's the label following the FDA's approval because this is -- and I guess you have to take my word for it, your Honor. This is on the FDA's website opposite the 2005 approval. So on the FDA's website of drugs at FDA, it shows the letter that we just looked at and this label. And if you look at "How Supplied," at the back of the label, it says, "5 milliliters in a 10 milliliter bottle."

THE COURT: Do you have two other examples?

05:00 MR. CORNFELD: There were two other examples. They were approvals on a CBE 30 of what is described as a new container closure system for Allergan's drug Alocril and also for its drug -- these are both eyedrop drugs -- its drug Alphagan-P. Those are cited in the brief and attached as exhibits.

Your Honor, the issue, as you described it before, on an affirmative defense where they're raising this on a motion to dismiss has to be whether it's clear, whether it's clear that they are preempted -- our claim is preempted and they

05:01 prevail. I don't think any of this is clear. For example, what counsel was just going through regarding changes in the size or shape of a container closure system that would change the sterility assurance. We know that they have done these approvals of changes in size or shape of container closure systems. Would the change in this instance affect the

sterility assurance? There's nothing in this record to establish that. It's their burden, as your Honor --

THE COURT: Say that again, please.

MR. CORNFELD: Okay. The question for the change in the container closure system, as counsel said and as we also agree, if it would affect the sterility assurance, it requires prior approval. The regulation says that. If it doesn't affect the sterility assurance, it would not require prior approval.

05:02 Would this change affect the sterility assurance? In other words, your Honor, would it make -- would it present a major potential for an adverse effect, to make these changes, an adverse effect in terms of sterility assurance. It's their burden to establish that. There's nothing in the record right now that can answer that one way or the other.

THE COURT: Well, now let me go back to, when you say would these changes have an adverse effect in terms of sterility assurance, what are you referring to, a regulation for guidance?

05:03 MR. CORNFELD: Yes, the regulation says --

THE COURT: Which regulation?

MR. CORNFELD: 314.70. It's in section (b). It's also in the guidance document.

THE COURT: Now I want to -- 314.70?

MR. CORNFELD: Section (b). If your Honor would give

me just a minute.

THE COURT: It says, "Changes that may affect drug substance or drug product sterility assurance, such as changes in drug substance, drug product, or component sterilization methods" are changes requiring prior approval, right?

MR. CORNFELD: It's Roman numeral iii, your Honor, (b)(iii), "Changes may affect drug substance or drug product sterility assurance, such as."

THE COURT: None of those such as's are contained --

05:04 MR. CORNFELD: I guess we're talking about the guidance document, your Honor.

THE COURT: Well, I thought that actually helped you. But then the guidance document from 2004 --

MR. CORNFELD: Yeah, yes.

THE COURT: -- "For sterile products, any change that may affect drug product sterility assurance, such as changes in the size and shape of a container for a sterile drug product," that's a major change requiring prior approval.

MR. CORNFELD: Right, yes, if it may affect drug

05:05 product sterility assurance. We know that not all changes to the size or shape of the container closure system will do that because we know that the FDA has approved changes in the size or shape. It did that in the case of Zymar.

THE COURT: Without requiring --

MR. CORNFELD: Without prior approval. It was on a

CBE 30.

THE COURT: So would it be correct to reframe your argument to say it's a factual issue as to whether changing in the size and shape of a container for a sterile product may affect drug product sterility?

MR. CORNFELD: Yes, your Honor. Yes. Thank you. I was hoping to be able to say that, but yes. Yes, it is a factual issue because there's nothing in the record to answer that based on the pleadings and based on --

05:06 THE COURT: Well, I think I can anticipate, but list it as an example of something that may affect --

MR. CORNFELD: They say that if it may affect sterility assurance, then it requires prior approval. If it's something that won't, and we know in the instance of Zymar --

THE COURT: No. It says, "For sterile drug product," so we're talking about a sterile drug product. It says, "Any change that may," not "any change that will," but "any change that may affect product sterility assurance such as changes in size and/or shape of a container for a sterile drug product." 05:07 So that seems to be saying that a change in the size or shape may affect sterility assurance and therefore requires prior approval.

MR. CORNFELD: Well, your Honor, I think in order to be able to answer that conclusively, it helps to look at what the FDA has done, what the companies have done in submitting

CBE 30s for the change in size or shape of a container closure system as a CBE 30, and what the FDA has done would show us how these companies and how the FDA interprets that regulation in real life. If it may affect the sterility assurance, it would be a major change, but not all changes to a container closure system size or shape will do that.

THE COURT: Perhaps not all will do that. But maybe all may do that.

MR. CORNFELD: Well, in the case of Zymar, they approved it on a CBE 30 with a change in -- we know the size. It went from 8 milliliters to 10 milliliters. We know that there were other container closure system changes that we cited.

05:08

THE COURT: All right. I gave the defendants a long time. I'll give you more time, too, but I think I'm not going to achieve my goal in deciding this issue today. You focused me on some issues that I'm going to do some more work on.

MR. CORNFELD: Your Honor, I believe we have shown, at least, this is not clear, as I said. We have also shown a basis -- we have at least one example of the FDA interpreting the regulation to mean that just because something is a change in the size or shape, it doesn't affect sterility assurance, and we should be entitled to discovery from their files to find other examples.

05:09

In one of our other cases we received partial

discovery from the plaintiffs -- excuse me, from the defendants and --

THE COURT: In which case?

MR. CORNFELD: In the *Eike* case in Illinois, those subject documents are subject to a protective order for confidentiality.

THE COURT: Was there a motion to dismiss in this case, in either of those other two cases?

MR. CORNFELD: Yes.

05:10 THE COURT: So there was a motion to dismiss based on preemption?

MR. CORNFELD: Yes.

THE COURT: It was granted in New Jersey.

MR. CORNFELD: Not on preemption. The Court didn't reach that issue.

THE COURT: On standing.

MR. CORNFELD: On standing. In the Southern District of Illinois the Court denied the motion to dismiss.

THE COURT: Do I have that decision?

05:10 MR. CORNFELD: You have it cited in the brief to the Court.

THE COURT: What's the name of it?

MR. CORNFELD: It's *Eike*, E-i-k-e. *Eike v. Allergan*, your Honor.

THE COURT: All right. Is there more you would like

to say now?

MR. CORNFELD: I think, unless your Honor has other questions or my co-counsel has something he thinks I should have said, no, your Honor. Thank you, your Honor.

THE COURT: I want to do -- I'm sorry. Is there something you wanted to say?

MS. JACXSENS: I was going to respond very briefly, your Honor, to the points he made about these documents.

THE COURT: Very briefly.

05:13 MS. JACXSENS: Very briefly. I first just wanted to point out that even on its face, none of these documents talk about the redesign of a dropper system that's never been submitted or approved by the FDA before, none of them on their face. You can see that. None of them talk about the redesign of a dropper.

The second point, I would like to refer your Honor to footnote 4 of our reply brief that addresses why these documents also do not make a difference. I'm happy to make that point very briefly.

05:13 THE COURT: Go ahead.

MS. JACXSENS: That point is that preemption is an issue of law, and you're looking at the conflict between the state law and the federal law. There may be situations where a particular regulator may not follow the guidance. But what *Mensing* says, it says at 2579, it said, "We can often imagine

that a third party or the federal government might do something that makes it lawful for a private party to accomplish under federal law what state law requires of it. If these conjectures suffice to prevent federal and state law from conflicting for supremacy clause purposes, it is unclear when outside of express preemption the supremacy clause would have any force."

And the third point just briefly, your Honor, is that in addition to that section that we focused on, the point
05:14 number 3 in the guidance, the sixth bullet point, this would also be considered a major change under part 3 of that section related to changes to a primary packaging component control if it's a dose delivered to the patient, as well as it would be considered a major change because of the issue that it would include half of the inactive ingredients and half of the dose.

THE COURT: Okay. I'm going to do the following. And given the large number of lawyers in the room, I don't think this will be an inordinate burden. I'm going to order you to order from the court reporter on an expedited basis the
05:15 transcript of this hearing, which has been helpful in focusing me but not sufficiently that I feel I can decide this matter orally. As I may have formulated earlier, the fact that something is complicated, lots of regulations, doesn't mean it may not be clear once I try to figure it out, so I want to do some more work to try to figure it out.

You filed a lot already. But would you like to have, say, roughly to next Wednesday, or something like this Thursday, to file something -- you know what questions I've asked you today. You've cited lots of documents. And you know, you might now present what you presented before in a more focused way. I was aware of your footnote, for example, the fact that somebody departed from the law doesn't mean the matter is not preempted. But the things you've emphasized right at the end here are not the things that were primarily emphasized in the brief. So I'll give you that chance. But I don't want to put this down for very long. I propose to at least tentatively see you again in two weeks, if the key participants can be here, because I'd like, if I can, to decide these matters orally. And then, you know, if I dismiss it, it's over. If I don't dismiss it, we can schedule the rest of the case.

05:17

So looking at my schedule at the moment, I don't have anything scheduled on Friday the 13th.

MR. STRAUSS: I've got a pretrial that day, your Honor. I don't know if there's another day that would work besides that particular Friday.

05:18

THE COURT: Well, there's not many. How about Thursday the 12th possibly? And since you're cooperating so well, perhaps I don't need every single one of you. I mean, defense counsel cooperate.

MR. CORNFELD: May I ask --

THE COURT: Hold on. Does anybody have a problem with the 12th? Apparently not?

MR. CORNFELD: Your Honor, do I correctly conclude from what you just said that you will simply be announcing your decision and not asking for more argument?

THE COURT: If I want more argument, I'll let you know.

2:00 on Thursday the 12th. Do you want an opportunity to file something further? Not raising anything, it shouldn't raise anything new. That wouldn't be fair. And I can't -- with all these lawyers, you must have thought of everything before today. But just organizing it to focus -- my tentative view is that, to be colloquial, this is the ball game. I don't at the moment see -- but I'm going to get more deeply into this, too -- that there's an argument for the generics that would prevail if the argument for the other defendants doesn't prevail. I may listen to you on that. I want to get more deeply into it, too. I'm not dismissing the Chapter 93A claim analysis. Essentially unjust enrichment or money received -- I've never heard -- it's not material if the case is -- not going to have a case over New York law on money received if the federal claims are preempted.

Without ruining your weekends and your lives or the weekends and lives of people who work for you, any

submissions -- and they don't need to be that long, and you can tell me where I'll find more elaborate -- you know, they shouldn't be more than 20 pages. But that's the usual limit anyway. What if I give you until November 4, which is Wednesday, or November 5, which is Thursday?

MS. JACXSENS: November 5 would be appreciated, your Honor. Just with the -- I know for me, with small kids with the holiday weekend.

THE COURT: That's fine.

05:21 MR. STRAUSS: Your Honor, I just have a question. I wasn't sure what you wanted us to do with the transcript.

THE COURT: I want you to order it on an expedited basis, and my guess is you'll get it Monday.

MR. STRAUSS: That's fine.

THE COURT: Probably no later than Tuesday.

MR. STRAUSS: That won't affect the 5th at all.

THE COURT: Right. And presumably somebody's been taking notes. The court reporter is good at this, and we're at page 72, so you'll get it Monday or Tuesday.

05:22 MR. STRAUSS: Great. I don't mean to -- if you're not finished, I'll sit down. I just have one question, but I can do it at any time.

THE COURT: Well, I'm also going to order the following; that say by the 9th, that you confer, tell me whether you've settled this case, but particularly -- I'll give

you --

(Phone interruption.)

THE COURT: I'm supposed to fine you for that.

MS. JACXSENS: I'm so sorry. I was looking at my calendar so I turned it on, your Honor. I apologize.

THE COURT: Let's say the 10th by 12:00 noon, I want you to, A, let me know if you've settled; and B, give me a schedule for the case to proceed, preferably jointly but separately if necessary. I assume that if the case is not dismissed and we go to class certification, it strikes me that there may be some complex class certification issues. Maybe we wouldn't go to class certification. I can foresee you may have different views on that. I don't know how we would proceed.

If I see you on the 12th and I don't dismiss the case, which is an open question, then I'm going to sit down with you and hopefully establish a schedule for the rest of the case or the next phase of the case. I'm somewhat concerned that there are three parallel cases, but I guess the parties are different in each case. The issues are the --

MR. CORNFELD: Your Honor, in this case and in the New Jersey case, the plaintiffs obviously are different, but the lawyers for the plaintiffs are the same. And the defendants are the same, and I believe the lawyers are all the same.

THE COURT: I'm just really thinking off the top of my head whether there's going to be any issues of fact or issue

preclusion, but maybe not.

MR. CORNFELD: They're all going on at the same time. I guess if one finished, there could be, if one finished before the others.

THE COURT: Well, if that were the case, some of us are wasting time and money. The Illinois case is the oldest case?

MR. CORNFELD: Yes, your Honor.

THE COURT: All right, is there anything else in this matter for today?

MS. BLADOW: No, your Honor.

MR. DeMOURA: Thank you very much, your Honor.

THE COURT: Mr. Bartlett will give you a copy of the usual scheduling order, but it's not really going to fit for the purposes of this case. You'll need something that's fine-tuned for a class action, but he'll give you that. Okay. Court is in recess.

(Whereupon the proceedings adjourned at 5:25 p.m.)

CERTIFICATE OF OFFICIAL REPORTER

I, Kelly Mortellite, Registered Merit Reporter and Certified Realtime Reporter, in and for the United States District Court for the District of Massachusetts, do hereby certify that pursuant to Section 753, Title 28, United States Code that the foregoing is a true and correct transcript of the stenographically reported proceedings held in the above-entitled matter and that the transcript page format is in conformance with the regulations of the Judicial Conference of the United States.

Dated this 2nd day of November, 2015.

/s/ Kelly Mortellite

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Kelly Mortellite, RMR, CRR

Official Court Reporter